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Appln. No.: 10/053,329
Amendment dated January 4, 2006
Reply to Final Office Action mailed October 4, 2005

REMARKS

The Office Action of January 25, 2005 has been carefully reviewed and this paper and RCE is Applicants' response thereto. Applicants respectfully request reconsideration of the Application in view of the foregoing Amendments and following Remarks.

Claims 80-86 and 89-107 are pending. Claims 1-79 and 110-135 are withdrawn. Claims 87-88 and 108-109 are cancelled. The Office Action objected to the drawings as failing to show all the features recited in the claim 85. The Office Action objected to the prior response because it allegedly added new matter into the disclosure. The Office Action rejected claims 80-86, 89-102 and 107 under 35 U.S.C. § 112, ¶ 1 as failing to comply with the written description requirement. The Office Action also objected to the specification as failing to provide proper antecedent basis for the claimed subject matter with regards to claims 95-98. The Office Action rejected claims 80-83, 85, 86, 89, 103 and 107 under 35 U.S.C. § 102(e) as being anticipated by U.S. Publication No. 2003/0069541 to Gillis *et al.* ("Gillis"). The Office Action rejected claims 80-81, 85, 86, 89, 90, 103, and 107 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,129,685 to Howard, III ("Howard"). The Office Action rejected claims 82-84, 91-102 and 104-106 under 35 U.S.C. § 103(a) as being unpatentable over Howard in view of U.S. Patent No. 5,711,316 to Elsberry *et al.* ("Elsberry").

In response, Applicants respectfully traverse the rejection with the following remarks:

Interview

The Applicants' representatives would like to express their appreciation for the time taken by the examiner to discuss this case. During the interview, the support for the pending claims was discussed and it was noted that claim similar to the currently pending claims were originally filed in the parent case, thus the currently pending claims were believed to have adequate written description support. In addition, it was agreed that more detailed citation to the incorporated references would be provided in this response to show the location of the support for the various features recited in the claims.

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In addition, the phrase "outwardly" was discussed and it was noted that as recited in the pending claims, outwardly means away from the central axis of the lumen as discussed in the specification as submitted on page 13, lines 1-4.

Objection to the Drawings

The drawings are objected to for failing to disclose every element of claim 85. In response, claim 85 has been amended, obviating this objection.

Support for Prior Amendments to the Specification

The Office Action indicated that the prior response did not provide a detailed citation to the location of the support for the amendments to the specification regarding the term "setting."

For the "setting" amendment, support is at least found in U.S. Patent No. 4,692,147 to Duggan ("Duggan"), C. 5, L. 1 - C. 6, L. 2, which was incorporated by reference in its entirety on page 20 of the specification as filed. See 37 C.F.R. § 1.57 (c) (allowing essential subject matter to be incorporated by reference). Accordingly, Applicants submit that the prior amendment to the specification did not add new matter and withdrawal of the objection to the amendment to the specification is respectfully requested.

Objection to the Specification

The Specification was objected to as failing to provide proper antecedent basis for the use of the term "setting" as used in claims 95-98. In response, Applicants first note that the previous response amended the specification to provide information on how the term setting was being used so as to provide antecedent basis for this term as used in claims 95-98. This amendment was made at the request of the Office Action mailed on January 25, 2005. The Final Office Action now requests that this amendment to the specification be removed, allegedly because it adds new matter, apparently because the prior response did not precisely note where in the incorporated reference support could be found. As noted above, the precise place in Duggan that provides support for the amendment to the specification has been provided. Therefore, Applicants respectfully submit that no new matter has been added. Applicants further respectfully submit the specification as previously amended does provide proper antecedent basis for the term "setting" as used in claims 95-98.

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Accordingly, withdrawal of this objection is respectfully requested.

Amendments to the Claims

Claims 80, 102 and 103 have been amended to clarify the intended scope of the claim. For example, claim 80 now recites "a cannula having a lumen distal end with a plurality of openings provided near the lumen distal end, each opening capable of directing a catheter outwardly along a distinct predetermined trajectory." Claims 102 and 103 have been similarly amended. No change in the scope of the claims was intended or believed made by these amendments.

Claim 85 has been amended to recite "wherein the therapy delivery device includes at least one catheter port coupled to a first and a second catheter, wherein the delivery system is configured to deliver at least two drugs through the first and second catheters." Support for this amendment is at least found on page 22, lines 1-3 of the specification as filed, thus no new matter has been added.

Rejection under 35 U.S.C. § 112, ¶ 1

The Office Action rejected claims 80-86, 89-102 and 107 under 35 U.S.C. § 112, ¶ 1 for failing to meet the written description requirement. The Applicants note that is not clear if claims 103-106 are also rejected, however, to the extent these claims are rejected, the following discussion applies equally to them. In particular, the Examiner has expressed concern regarding the catheters protruding from the cannula as recited in claim 80, determining liquid infusion rates as recited in claim 91, the use of parameters and settings as recited in claims 92-98, the sensor recited in claim 104, and the treatment of a neurological disorder using a catheter and fluid delivery. Applicants respectfully submit that the present application finds support for each of these features as discussed below.

As an initial matter, as noted above, the prior originally filed claims in the parent application recite similar features, thus these originally filed claims provide support for the claims pending in this application.

In addition, Applicants note that on page 5 of the specification as filed, it is explained that an alternative embodiment the present invention is directed towards a drug delivery system

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and that the therapy delivery element may be a catheter. Thus, plainly the specification is directed toward a drug delivery system. In addition, the specification on pages 21-22 explains that the leads can be used to deliver drugs as well as electrical stimulation. Thus, the specification as filed makes it clear that wherever a lead is depicted it can provide electrical stimulation or a drug or both. Applicants submit that it is inherent that such a lead would be a catheter if it is to supply a drug as Applicants are unaware of any way to transmit a drug from a pump to a particular location within a patient without using a catheter or an equivalent structure.

Turning to the specifics issues mentioned, Figure 8 of the specification as filed illustrates an embodiment of a cannula having a lumen distal end, the lumen distal end having a plurality of openings, each opening capable of directing a catheter outwardly along a distinct predetermined trajectory extending outwardly. While Figure 8 depicts the leads as being used for electrical stimulation, as noted above, these leads may be catheters. Thus, Applicants respectfully submit that the present application provides support for the catheters protruding from the cannula as recited in claim 80.

Regarding the features recited in claim 91-98 directed toward the port, sensor and processor control, the Office Action argues that Elsberry discloses these limitations while rejecting the pending claims under 35 U.S.C. § 103(a). Applicants respectfully submit that, as Elsberry has been incorporated by reference in its entirety into the pending application (see page 14, lines 13-15 of the specification as filed), the pending application also provides support for these features.

With regard to the treatment of various diseases, the present application discusses the treatment of neurological disorders on pages 19. In addition, Elsberry discloses an example of treating a neurological disorder with a drug. (Elsberry, Abstract).

Regarding the alleged lack of support for "determining liquid infusion rate through first and second catheters with a parameter and signal level" in claim 91, support at least is found in Elsberry, C. 7, L. 49-53, which is incorporated by reference into the current application.

Regarding the alleged lack of support for "use of parameters and settings to control liquid infusion" in claims 92-98, support for this is at least provided in Duggan, C. 5, L. 1 - C. 6, L. 2,

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which was incorporated by reference into the current application and discloses methods of controlling a pump.

Regarding the alleged lack of support for "the sensor in the proximity of liquid delivery position" in claim 104, support is at least found in Elsberry, C. 4, L. 1-42.

As the incorporation by reference of essential and non-essential subject matter from U.S. Patents is in accordance with the procedures provided for in the MPEP 608.01(p) and is authorized by 37 C.F.R. § 1.57 (c), Applicants respectfully submit that the current application contains sufficient written description support to show the inventors had possession of the claimed invention at the time of filing. Therefore, withdrawal of this ground of rejection is respectfully requested.

Rejection Under 35 U.S.C §102(b) - Gillis

Claims 80-83, 85-86, 89, 103 and 107 were rejected as anticipated by Gillis. While not addressing the issue of whether Gillis can be properly considered prior art for the present pending application (but reserving the right to do so), the rejection is respectfully traversed below.

The Office Action suggested that Gillis "discloses a delivery system having a first and second catheters 60 protruding from a multiple opening cannula 10." The Office Action also suggests that Gillis discloses openings capable of directing the catheters in distinct trajectories. Assuming, without admitting so, that this is true, the Office Action has only provided support for the notion that it was known to use a single cannula with two catheters protruding from two openings in the cannula along the same trajectory as the cannula. Applicants respectfully submit that even if Gillis was somehow construed to be capable of provide distinct trajectories, the trajectories certainly would not be predetermined because both openings in the cannula are configured to direct catheters along the same trajectory as the cannula and any change would be due to random chance. Pending claim 80 recites "a cannula having a lumen distal end with a plurality of openings provided near the lumen distal end, each opening capable of directing a catheter outwardly along a distinct predetermined trajectory." The Office Action has failed to address the underlined features. For example, Applicants note that the trajectory provided for the catheters in Gillis is not outwardly as recited in the pending claims (i.e. not directed out from the

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central axis of the lumen) and if the catheter were to go outwardly, the direction would not be predetermined. Thus, for at least the above reasons Gillis fails to disclose all the limitations of claim 80. As Gillis does not disclose all the limitations of claim 80, Gillis cannot be said to anticipate claim 80.

Independent claim 103 also recites the above limitation, therefore, Gillis cannot be said to anticipate claim 103 for at least the same reasons Gillis does not anticipate claim 80.

Claims 81-83, 85-86 and 89 depend from claim 80 and necessarily include at least one limitation not disclosed by Gillis, therefore Gillis cannot fairly be said to anticipate claims 81-83, 85-86 and 89.

Claim 107 depend from claim 103 and necessarily include at least one limitation not disclosed by Gillis, therefore Gillis cannot fairly be said to anticipate claims 107-109.

Accordingly, withdrawal of this ground of rejection is respectfully requested.

Rejection Under 35 U.S.C. § 103(a) – Howard & Elsberry

Claims 80, 81, 85, 86, 89, 90, 103, and 107 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Howard. Claims 82-84, 91-102 and 104-106 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Howard in view of Elsberry. Thus, all the pending claims stand rejected under 35 U.S.C. § 103(a) in view of Howard, alone or in combination with Elsberry.

The Office Action suggested that the prior response misinterpreted the use of Howard and that the Office Action was modifying Figure 30 with the teaching provided in Figures 23 and 25. The Office Action further suggested that the figures could be combined because of the "nature of mechanical arts and their combinability." These figures are provided below.

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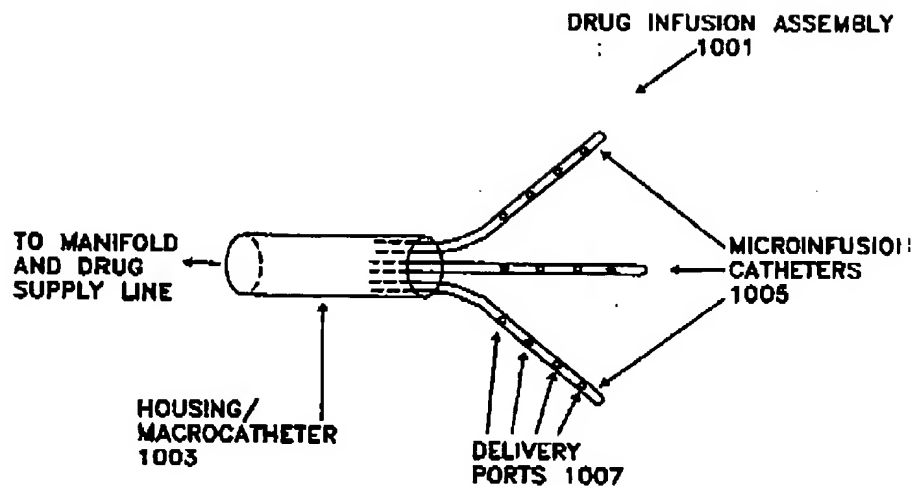


FIG. 30

(Howard, Figure 30). As can be plainly seen, Figure 30 illustrates multiple microinfusion catheters 1004 extending from a single opening in a macrocatheter 1003. However, claim 80 recites "a cannula having a lumen distal end with a plurality of openings provided near the lumen distal end, each opening capable of directing a catheter outwardly along a distinct predetermined trajectory." Figure 30 fails to show the plurality of openings and also fails to show openings that are capable of directing the catheter outwardly along predetermined trajectories as recited in the pending claims. Nor does Figure 25 help to correct the deficiency in Figure 30. Figure 25 is provided below:

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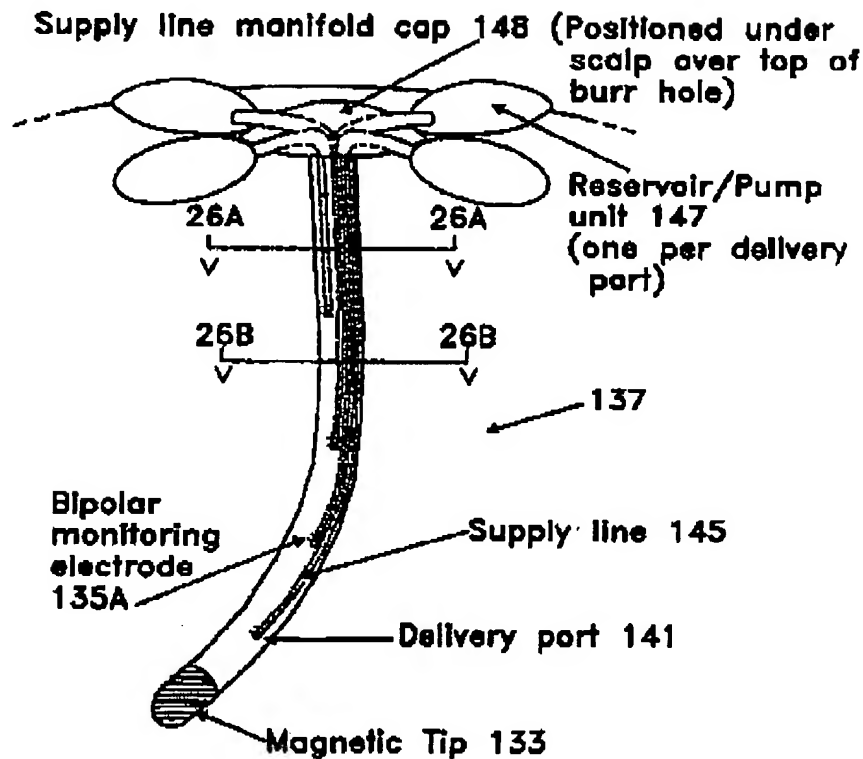


FIG. 25

(Howard, Figure 25). As is plain, the supply lines do not extend from the electrode but rather end at a delivery port. Nor can these ports be fairly argued to be "capable of directing a catheter outwardly along a distinct predetermined trajectory" as is recited in the pending claim.

Regarding the Office Action's suggest that these distinct concepts could be combined, Applicants first respectfully submit that there does not appear to be any support for such a combination. In addition, Applicants cannot readily envision how Figures 25 and 30 could somehow be modified to form the present invention. Figure 25 discloses supply lines leading to ports, not catheters positioned within a cannula, and it does not appear that these supply lines could be configured to direct catheter out the delivery ports. Thus, combining Figures 23 and 30 would simply produce a cannula with several catheters extending from the end (as depicted in Figure 30) and several supply lines ending at delivery ports in the side of the cannula (as

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depicted in Figure 25). Therefore, even the cannulas of Figures 30 and 25 were combined, the combination would still not include all the limitations of the pending claims.

Regarding Elsberry, the Office Action did not suggest Elsberry discloses a "a cannula having a lumen distal end with a plurality of openings provided near the lumen distal end, each opening capable of directing a catheter outwardly along a distinct predetermined trajectory." Therefore, the addition of Elsberry to Howard fails to correct the above noted deficiency. Accordingly, neither Howard nor Elsberry disclose the limitation of "a cannula having a lumen distal end with a plurality of openings provided near the lumen distal end, each opening capable of directing a catheter outwardly along a distinct predetermined trajectory." Therefore, the Office Action fails to establish a *prima facie* case of obviousness. Thus, claim 80 cannot be considered obvious in view of Howard and Elsberry.

The remaining pending independent claims 102 and 103 recite the limitation "a cannula having a lumen distal end with a plurality of openings provided near the lumen distal end, each opening capable of directing a catheter outwardly along a distinct predetermined trajectory." As noted above, Howard fails to disclose, suggest or teach such a feature and the addition of Elsberry does not correct this deficiency. Therefore, Howard, alone or in combination with Elsberry, fails to disclose, suggest or teach all the limitations of the pending independent claims 80, 102 and 103. As Howard, alone or in combination with Elsberry fails to disclose all the limitations of claims 80, 102 and 103, the combination of Howard and Elsberry cannot be said to make claims 80, 102 and 103 obvious.

The remaining pending claims 81-101 and 104-109 depend from claim 80 and claim 103, respectively, and necessarily include at least one limitation not disclosed, suggested or taught by Howard, alone or in combination with Elsberry for the reasons discussed above with regard to the independent claims.

Accordingly, withdrawal of this ground of rejection for claims 80-86 and 89-107 is respectfully requested.

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All rejections having been addressed, the Applicant respectfully submits that the instant application is in condition for allowance, and earnestly solicits prompt notification of the same.

Respectfully submitted,

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Dated: January 4, 2006

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